PATENT
Docket No. 348022000201

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Tatania Grollman

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In the application of:

Daniel R. HENDERSON and
Eric SCHUUR

Serial No.: To Be Assigned

Filing Date: December 5, 2000

For: TISSUE SPECIFIC ADENOVIRAL VECTORS

Examiner: To Be Assigned

Group Art Unit: To Be Assigned

PRELIMINARY AMENDMENT

Assistant Commissioner for Patents
Box Patent Application
Washington, D.C. 20231

Dear Sir:

Prior to examination on the merits, Applicants respectfully request entry of this Preliminary Amendment for the above-captioned patent application prior to calculation of fees.

AMENDMENTS

In the specification

Page 1, under "Cross Reference to Related Applications", please delete that paragraph (lines 11-23) and substitute the following:

--This application is a continuation of application serial no. 09/151,376, filed September 10, 1998, which is a continuation-in-part of application serial no. 08/669,753, filed June 26, 1996, which is a continuation-in-part of application serial no. 08/495,034, filed June 27, 1995, the disclosure of which is herein incorporated by reference. This application is also a continuation-in part of application serial number 09/033,428, filed March 2, 1998, which claims the benefit of provisional application serial number 60/039,597, filed March 3, 1997; and a continuation-in-part of application serial number 09/033,555, filed March 2, 1998, which claims the benefit of provisional application serial number 60/039,763 filed March 3, 1997; and a continuation-in-part of application serial number 09/033,333, filed March 2, 1998, which claims the benefit of provisional application serial number 60/039,762, filed March 3, 1997. All of the above patent applications are incorporated by reference herein.--

In the claims

Please cancel claims 9-54 without prejudice or disclaimer.

Please add the following new claims:

55. (New) The adenovirus vector of claim 3, wherein the adenovirus early gene is E2.

56. (New) The adenovirus vector of claim 2, wherein the TRE is selected from the group consisting of a promoter and an enhancer.

57. (New) The adenovirus vector of claim 2, wherein the cell-type specific TRE is selected from the group consisting of an alpha fetoprotein TRE, a DF3-TRE, a tyrosinase-TRE, a CEA-TRE, a surfactant protein-TRE, and an ErbB2-TRE.

58. (New) The adenovirus vector of claim 56, wherein the promoter is selected from the group consisting of alpha fetoprotein, DF3, tyrosinase, CEA, surfactant protein, and ErbB2 promoters.

59. (New) The vector of claim 2, wherein said vector contains a heterologous coding sequence that is expressed from said vector.

60. (New) The vector of claim 2, wherein said vector is encapsulated in an adenovirus coat.

61. (New) An cell comprising an adenovirus vector comprising an adenovirus gene essential for adenoviral replication under transcriptional control of a cell type-specific transcriptional response element (TRE), wherein said adenovirus gene essential for adenoviral replication is selected from the group consisting of E1A, E1B, E2 and E4, and wherein said TRE functions in said cell so that replication of the vector occurs in said cell.

62. (New) The cell of claim 61, wherein said TRE is selected from the group consisting of a promoter and an enhancer.

63. (New) The cell of claim 62, wherein the promoter is selected from the group consisting of alpha fetoprotein, DF3, tyrosinase, CEA, surfactant protein, and ErbB2 promoters.

64. (New) The cell of claim 61, wherein said cell is a tumor cell.

65. (New) The cell of claim 61, wherein said vector encodes a heterologous gene product, and wherein said vector expresses said heterologous gene product in the cells of a target tissue.

66. (New) The cell of claim 65, wherein said heterologous gene product provides anti-tumor activity in the cells of said tissue.

67. (New) A method of producing a cell-type specific adenovirus vector, said vector comprising an adenovirus gene essential for adenoviral replication under transcriptional control of a cell-type specific TRE, comprising culturing the cell of claim 61 and recovering said vector from said cell.

68. (New) An cell comprising a cell-type specific adenovirus vector encapsulated in an adenovirus coat, said vector comprising an adenovirus gene essential for adenoviral replication under transcriptional control of a cell type-specific transcriptional response element (TRE), wherein said adenovirus gene essential for adenoviral replication is selected from the group consisting of E1A, E1B, E2 and E4, and wherein said TRE functions in said cell so that replication of the encapsulated vector occurs in said cell.

69. (New) The cell of claim 68, wherein said TRE is selected from the group consisting of a promoter and an enhancer.

70. (New) The cell of claim 69, wherein the promoter is selected from the group consisting of alpha fetoprotein, DF3, tyrosinase, CEA, surfactant protein, and ErbB2 promoters.

71. (New) The cell of claim 68, wherein said cell is a tumor cell.

72. (New) The cell of claim 68, wherein said encapsulated vector encodes a heterologous gene product, and wherein said vector expresses said heterologous gene product in the cells of a target tissue.

73. (New) The cell of claim 72, wherein said heterologous gene product provides anti-tumor activity in the cells of said tissue.

74. (New) A method of producing a cell-type specific adenovirus vector encapsulated in an adenovirus coat, said vector comprising an adenovirus gene essential for adenoviral replication under transcriptional control of a cell type-specific transcriptional response element (TRE), comprising

(a) culturing a cell comprising a cell-type specific adenovirus vector encapsulated in an adenovirus coat, said vector comprising an adenovirus gene essential for adenoviral replication under transcriptional control of a cell type-specific transcriptional response element (TRE), wherein said adenovirus gene essential for adenoviral replication is selected from the group consisting of E1A, E1B, E2 and E4, and wherein said TRE functions in said cell so that replication of the encapsulated vector occurs in said cell; and

(b) recovering said encapsulated adenoviral vector from the culture.

75. (New) A producer cell line comprising the cell of claim 61.

76. (New) A producer cell line comprising the cell of claim 68.

REMARKS

By this amendment, claims 9-54 have been cancelled and new claims 55-76 have been added. Support for the new claims is found in the specification, *inter alia*, at page 50, lines 3-4; page 13, lines 1-3; pages 32-38; page 19, lines 8-11; pages 40-42; page 12, lines 1-13; page 9, lines 12-15; page 16, line 20 to page 17, line 6; page 45, line 1, to page 46, line 12; page 45, lines 10-13; page 23, lines 16-25; page 51, lines 1-2; and the Examples.

Applicants bring to the Office's attention U.S. Patent No. 5,998,205 (enclosed). In order to comply with 35 USC 135(b), Applicants are presenting to the Office claims which correspond to claims of the '205 patent.

In the unlikely event that the transmittal letter is separated from this document and the Patent Office determines that an extension and/or other relief is required, applicants petition for any required relief including extensions of time and authorizes the Assistant Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing docket no. 348022000201. However, the Assistant Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

Respectfully submitted,

Dated: December 6, 2000

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